



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/596,159 | 06/01/2006 | Hans Smola | 112701-731 | 2943 |
| 29157 | 7590 | 03/04/2009 | EXAMINER | |
| K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690 | | | | PURDY, KYLE A |
| ART UNIT | | PAPER NUMBER | | |
| | | 1611 | | |
| NOTIFICATION DATE | | | DELIVERY MODE | |
| 03/04/2009 | | | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/596,159 | SMOLA ET AL. | |
| | Examiner | Art Unit | |
| | Kyle Purdy | 1611 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01/14/2009.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the arguments filed on 01/14/2009.
2. Claims 1-5 are presented for examination on the merits. Claims 6-11 stand as withdrawn.

The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 01/14/2009 regarding the rejection of claims 1-5 made by the Examiner under 35 USC 103(a) over McEwen et al. (US 6194379) in view of Gray et al. (US 5714472) have been fully considered but they are not found persuasive.

4. The rejection of claims 1-5 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 10/16/2008.

5. In regards to the 103(a) rejection, Applicant asserts the following:

A) Gray does not disclose or suggest a nutritional composition comprising at least 3% of the total calories of the composition being proline; and

B) The Examiner has applied hindsight reasoning to the limitation that the compositions comprise at least 3% of the total calories as arginine because Gray teaches away from such an amount.

6. In response to A, the Examiner agrees that Gray teaches the 25% of the total caloric content is to be due to protein wherein 4-6% of the protein is to contain proline. It's noted that this comes out to about 1.5% of the caloric content. However, Gray also states that in another embodiment, the proline content is at least 2.0% of the total calories of the composition. This particular teaching provides substantial overlap with the present claims, i.e. 3% and above. The

MPEP states that in cases where the claimed ranges “overlap” ranges disclosed by the prior art, a *prima facie* case of obviousness exists. See MPEP 2144.05. Thus, while it may be true that Gray does not specially disclose or suggest ‘at least 3%’, it would have been readily obvious to any person of ordinary skill that the caloric percentage due to proline could be adjusted to values greater than 1.5% and greater than 2%. Thus, if one were to endeavor to create a composition with a composition with a caloric proline content of 2.5%, 3% or 5%, it would not have been a product of innovation but rather one of ordinary skill and common sense. Applicants argument is not persuasive.

7. In response to B, the Examiner disagrees with Applicants characterization that the combination of references amounts to hindsight as there would have been no reason to combine them. Gray and McEwen are both nutritional formulations for accelerating wound healing. This commonality would provide sufficient motivation to combine the two teachings. In regards to the caloric content of arginine, McEwen teaches that arginine present in amount of about 1% of the total caloric content of the composition is useful for enhancing wound healing and providing positive nitrogen retention after injury. Thus, even though Gray teaches using arginine in amount greater than 1.8%, one of ordinary skill in the art would have been sufficiently capable of looking to the art for similar compositions, find McEwen and modify the teaching of Gray such that the composition would comprise less than about 1.8% of the caloric content due to arginine and have a reasonable expectation that the resultant composition would effectively treat wounds and provide a positive nitrogen balance in said wounds. Applicants argument is not persuasive.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen et al. (US 6194379; of record) in view of Gray et al. (US 5714472; of record).

10. Gray is also directed to nutritional compositions for enhancing wound healing. The composition comprises a carbohydrate, a lipid and a protein source (see abstract). The protein source is to comprise about 28% of the caloric content for the composition (see column 3, line 65; see instant claim 4). The composition is also to have an energy density of at least 1.3 kcal/mL (see column 2, lines 15-20; see instant claim 5). It is taught that a high caloric content is useful because it imparts energy to the user. The composition is also taught to contain proline at a caloric percentage of between 4 and 6% (see column 4, lines 63-65; see instant claims 1 and 2). It is taught that proline is useful for accelerating and promoting wound healing and tissue repair/cellular division (see column 4, line 55).

11. Gray fails to teach the composition as comprising less than 1.8% of the total calories due to arginine.

12. McEwen is directed to nutritional formulations comprising a protein source, a lipid source and a carbohydrate source (see Example 1). Example 1 teaches a formulation that comprises sucrose, canola oil and arginine. It is taught that arginine is to comprise about 1% of the total caloric content of the composition (see column 9, lines 1-5; see instant claims 1 and 3).

It is noted that the arginine at such a caloric percentage is capable of accelerating wound healing and nitrogen retention after injury.

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Gray and McEwen with a reasonable expectation for success in arriving at a composition comprising a lipid, a protein and a carbohydrate wherein the composition comprises less than 1.8% of the caloric content is attributed to arginine. One would have been motivated to supplement the teaching of Gray with McEwen because the composition would accelerate the healing of wounds and aid in the retention of nitrogen. Therefore, a composition comprising a protein, a carbohydrate and a lipid wherein the composition attributes less than 1.8% of its caloric content to arginine is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
February 24, 2009*

*/David J Blanchard/
Primary Examiner, Art Unit 1643*